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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,544	11/12/2003	Linda S. Powers	13368.0001 (DIV. IV)	6901

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K. S. Cornaby
Suite 1500
170 South Main Street
Salt Lake City, UT 84101-1644

EXAMINER

LUCAS, ZACHARIAH

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 02/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/706,544

Applicant(s)

POWERS ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11-12-03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II (methods for the capture of a virus on a substrate), and species D (wherein the ligand for the virus is a peptide specific for an outer membrane protein), in the reply filed on December 21, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claim 1 is under consideration to the extent that it reads on, or is generic to the elected invention.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on November 12, 2003, is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Objections

4. Claim 1 is objected to because of the following informalities:
a comma should be inserted between the terms "conjugated lipids" and "prion" in line 4 of the claim; and
a comma should be inserted between the terms "prion" and "and microbial protein targets" in line 9 of the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 provides for a method for the capture of a biological analyte onto a substrate, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 1 is also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

8. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the

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invention. This claim provides for a method of capturing a biological analyte onto a substrate. However, subparts (e)-(k) of the claim each provide for an alternative intended use for the claimed method. It is unclear if the Applicant intended that the claimed method requires each of the different embodiments indicated by these subparts to the claim, or if the Applicant intended that these be alternative embodiments. Clarification is required.

9. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the following limitation: "the ligands used" in line 2 of the claims. There is insufficient antecedent basis for this limitation in the claim.

10. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim reads on methods for the capture of virus to a substrate using a ligand that may be a "peptide specific for outer membrane proteins." It is noted that the application does not appear to provide any limitation on what form such peptides may take. However, the application does indicate that the "present invention describes the capture of microorganisms and their proteinaceous toxins using non-antibody based ligands." It is therefore unclear whether the claims are intended to be limited to such "non-antibody based ligands," or if the claims are intended to include such antibody based ligands as potential peptides specific for the outer membrane proteins.

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For the purposes of this action, because the claims do not appear to be limited to non-antibody based ligands,” the claims are read as including the use of such antibody-based ligands.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim was amended in a preliminary amendment filed on November 12, 2003 such that the claim now reads on subject matter that is not supported in the application as filed. I.e., the claim has been amended to read on the following embodiments of the claimed inventions which are not supported by the application as filed:

embodiments wherein the ligand used in the method, or the analyte to be detected, is a prion;

embodiments wherein the substrate is used for the concentration of analytes from veterinary samples, an aerosol, food product slurries, food ingredient slurries, and soil slurries. It is noted that the preliminary amendment was filed with the application. However, the application was filed as a division of prior application 09/999,159 (which does not provide support for the

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newly added subject matter), along with a copy of the oath/declaration from the parent. Although amended rule 37 CFR 1.115 indicates that, in applications filed on or after September 21, 2004, a supplemental oath or declaration may be filed to account for preliminary amendments filed with the application, such is not the case in applications, such as the present application, that were filed prior to September 21, 2004. See, 69 (182) Federal Register 56518 (left column, first full paragraph). The subject matter added by the preliminary amendment of November 12, 2003 is therefore considered New Matter to the application.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over PCT publication WO 98/49557, naming Powers et al. as inventors. The rejected claim reads on a method capturing a virus to a substrate surface with a ligand, wherein the ligand is specific to an outer membrane protein.

Powers et al teaches a method of detecting analytes in a sample by contacting the sample to a series of ligands tethered to a surface. Among the ligands taught by the reference are those that bind to proteins of the outer membrane of microbial cells. See, pages 6-11. The reference also teaches that the analyte to be detected may be a virus. See e.g., claim 11. Thus, the reference

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renders obvious the use of such ligands for the use of capturing a virus to a surface. Although the present application identifies preferred lengths for tethers linking the ligand to the substrate, such limitations are obvious as one skilled in the art would know to maximize the effectiveness of such an assay by adjusting the length of the tether to account for the size of the target analyte. See e.g. U.S. Patent 6,124,102, column 18, lines 19-64 (cited in the IDS filed November 12, 2003).

2. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Klempner et al. (U.S. Patent Application Publication U.S. 2002/0187464. The rejected claims read on a method for capture of a virus to a substrate using a peptide ligand specific to outer membrane proteins thereof.

Klempner teaches the use of affinity ligand reagents (ALRs) for the detection of biological constructs. See e.g. page 1, paragraph 0006; page 2, paragraph 0016; and page 3, paragraph 0022. The reference discloses ALRs as being antibodies, small organic molecules, or polypeptides, and that at least 10 different ALRs specific for each analyte to be detected. Page 2, paragraph 0017. Klempner also teaches that the disclosed method may be used as a method that “fingerprints” microorganisms through identification of the molecules on their outer surfaces. Page 7, paragraph 0066. See also, Wang et al., U.S. 5,922,617 (indicating in column 7, lines 53-59, that those in the art would have recognized ALRs that bind to virus surface membrane proteins as obvious embodiments). Thus, the reference renders obvious the use of peptides that binds to the outer membrane proteins of the microorganism to be detected. Finally, the reference teaches that among the biological constructs that can be detected by the method taught by

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Klempner are viruses. Page 1, paragraph 0006. Because the reference teaches that the described ALRs may be used to bind the target virus to the substrate, the reference renders obvious the capture of the virus onto the substrate.

Klempner further teaches that the ALRs may be covalently or non-covalently attached to a substrate surface. Page 6, paragraph 0050. Thus it would have been obvious to one of ordinary skill in the art to covalently attach ligands used in the assay to the surface. Although the present application identifies preferred lengths for linkers (tethers) joining the ligand to the substrate, such limitations are obvious as one skilled in the art would know to maximize the effectiveness of such an assay by adjusting the length of the tether to account for the size of the target analyte. See e.g. U.S. Patent 6,124,102, column 18, lines 19-64. Because the reference teaches the claimed methods, and uses the claimed materials to perform the same function, the methods disclosed therein render obvious the invention as described by the identified claims.

14. It is noted that similar obviousness rejections to those above was presented in the parent application, and that the Applicant submitted an Affidavit or declaration to overcome the rejections on the basis of the length of the tether between the ligand and the substrate. Affidavits or declarations, such as those submitted under 37 CFR 1.131 and 37 CFR 1.132, filed during the prosecution of the parent application do not automatically become a part of this application. Where it is desired to rely on an earlier filed affidavit or declaration, the applicant should make the remarks of record in the later application and include a copy of the original affidavit or declaration filed in the parent application.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6, 21, 23, and 27 of U.S. Patent No. 6,780,602. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent represent a species of the presently claimed invention, and would anticipate the claims of the present application is applied as prior art. Because the current claim is generic to the claims of the patent, it is rejected for obviousness type double patenting.

17. Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, and 8 of copending Application No. 10/706,542. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application read on overlapping subject matter that would have anticipated the present claim if applicable as prior art. Because the current claim is generic to the claims of the patent, it is rejected for obviousness type double patenting.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21 copending Application No.

10/706,542. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application read on overlapping subject matter that would have anticipated the present claim if applicable as prior art. Because the current claim is generic to the claims of the patent, it is rejected for obviousness type double patenting. It is noted that the claims of the copending application do not state the biological analyte is a virus, or that the ligand is a specific to a outer membrane protein thereof. However, such embodiments are disclosed by the specification of the copending application. See e.g., page 7, and the abstract.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

19. No claims are allowed.

20. The following prior art reference is made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

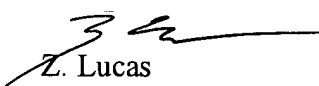
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Bryan et al., U.S. Patent 6,458,547. This reference provides teachings similar to those of Powers or Klempner above. See e.g., columns 12-14. The reference is therefore considered redundant to those of the other references.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


JAMES HOUSEL 2/7/05
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600